

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D0701648	(X3) Date Survey Completed 02/19/2025
Name of Provider or Supplier Wsu Infectious Disease Laboratory	Street Address, City, State 275 E Hancock Street Room 039, Detroit, MI	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D3029	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(2)</p> <p>Test procedures. Retain a copy of each test procedure for at least 2 years after a procedure has been discontinued. Each test procedure must include the dates of initial use and discontinuance.</p> <p>This STANDARD is not met as evidenced by: . Based on record review and interview with the technical supervisor, the laboratory failed to include the dates of discontinuance on test procedures for one (gram stains) of one test procedure not listed on the laboratory's test menu. Findings include: 1. A review of the laboratory's test procedures revealed a section titled "Gram Stain Quality Control" with the laboratory director's signature and initiation date of 1/23/25 and no discontinuation date stating, "Fresh reagents are maintained in the lab ad lot numbers are recorded. Package inserts are included in the procedures notebook as a reference. Known gram negative (E. coli) and gram positive (yeast) organisms are tested in parallel with each clinical specimen." 2. A review of the laboratory's test menu revealed a lack of gram staining listed. 3. An interview on 2/19/25 at 10:55 am with the technical supervisor confirmed gram staining was no longer performed, and the laboratory had not indicated the date of discontinuance on applicable test procedures.</p>
D5415	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)</p> <p>(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (c)(1) Identity and when significant, titer, strength or concentration. (c)(2) Storage requirements. (c)(3) Preparation and expiration dates. (c)(4) Other pertinent information required for proper use.</p>

This STANDARD is not met as evidenced by:

. Based on record review and interview with the technical supervisor, the laboratory failed to label reagents and solutions to include the expiration dates for four containers observed in the laboratory. Findings include: 1. The surveyor observed four reagent and solution containers in the laboratory on 2/19/25 at 9:03 am that lacked expiration dates: a. Two glass containers labeled as "Sterile DI H₂O 11/26/24". b. Two plastic squirt bottles labeled "70% Ethanol" and "Distilled H₂O" respectively. 2. An interview on 2/19/25 at 10:55 am with the technical supervisor confirmed the reagents and solutions listed above lacked expiration dates.